Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2005 list were published in the Federal Register in February 2005.

New Approvals

NADA Number: 141-238

Trade Name:	Spectramast™ LC
Ingredients:	Ceftiofur hydrochloride
Sponsor:	Pharmacia & Upjohn Co., a Division of Pfizer Inc.
Approval Date:	February 9, 2005
Status:	Prescription only
Route:	Intramammary
Species:	Cattle, lactating dairy
Drug Form:	Liquid (suspension)
Concentration:	12.5 milligrams ceftiofur hydrochloride equivalent per milliliter
Indications:	For the treatment of clinical mastitis associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*. Cows with systemic clinical signs caused by mastitis should receive other appropriate therapy under the direction of a licensed veterinarian.
Tolerance:	*21CFR 556.113* Ceftiofur: Tolerances are established for residues of desfuroylceftiofur (marker residue) inedible cattle tissue at: 8 parts per million in kidney (target tissue), 2 parts per million in liver, 1 part per million in muscle, 100 parts per billion in milk, and 166 parts per million for the injection site muscle.
Withdrawal:	Zero days; Milk – 72 hours
Exclusivity:	3 years

21CFR 526.314

ANADA Number: 200-280

Pioneer Product:	119-807
Trade Name:	Euthanasia-III Solution
Ingredients:	Pentobarbital sodium, phenytoin sodium
Sponsor:	Med-Pharmex, Inc.
Approval Date:	February 3, 2005
Status:	Prescription only
Route:	Intravenous, intracardiac
Species:	Dogs
Drug Form:	Liquid (solution)
Concentration:	390 milligrams pentobarbital sodium and 50 milligrams phenytoin sodium per milliliter
Indications:	For humane, painless, and rapid euthanasia.

21CFR 522.900

Actions Taken by FDA Center for Veterinary Medicine

ANADA Number: 200-326

Pioneer Product:	134-314
Trade Name:	Bimectin™
Ingredients:	Ivermectin
Sponsor:	Cross Vetpharm Group, Ltd.
Approval Date:	January 19, 2005
Status:	Over-the-counter
Route:	Oral
Species:	Horses, not intended for human consumption
Drug Form:	Paste
Concentration:	1.87%
Indications:	For effective treatment and control of the following parasites in horses: **Large Strongyles** (adults) – *Strongylus vulgaris* (also early forms in blood vessels), *S .edentatus* (also tissue stages), *S. equinus*; *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*; **Small Strongyles** (adults , including those resistant to some benzimidizole class compounds and fourth-stage larvae) – *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*; *Cylicocyclus* spp. including *C. insigne, C. leptostomum, C. nassatus,* and *C. brevicapsulatus*; *Cylicodontophorus* spp.; *Cylicostephanus* spp. including *C. calicatus, C. goldi, C. longibursatus,* and *C. minutus*; **Pinworms** (adults and fourth-stage larvae) – *Oxyuris equi*; **Ascarids** (adults, third-stage and fourth-stage larvae) *Parascaris equorum*; **Hairworms** (adults): *Trichostrongylus axei*; **Large-mouth Stomach Worms** (adults) – *Habronema muscae*; **Bots** (oral and gastric stages) – *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; **Lungworms** (adults and fourth-stages larvae) – *Dictyocaulus arnfieldi*; **Intestinal Threadworms** (adults) – *Strongyloides westeri*; **Summer Sores** caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; **Dermatitis** caused by neck threadworm microfilariae, *Onchocerca* sp.

21CFR 520.1192

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 038-233

Approval Date: January 14, 2005

This application provides for revised labeling warning against the use of these products in calves to be processed for veal.

21CFR 522.2680

NADA Number: 141-192

Approval Date: January 14, 2005

This application provides for revised labeling warning against the use of these products in calves to be processed for veal.

21CFR 522.2680

Actions Taken by FDA Center for Veterinary Medicine

ANADA Number: 200-287

Approval Date: January 21, 2005

This application provides for an additional container size.

21CFR 524.1044g

ANADA Number: 200-346

Approval Date: January 14, 2005

This application provides for an additional higher concentration (200 mg trenbolone acetate and 20 mg estradiol) when used in heifers fed in confinement for slaughter.

21CFR 522.2477

Change of Sponsor

NADA Number(s): 140-270

From: Boehringer Ingelheim Vetmedica, Inc.
To: Phoenix Scientific, Inc.

Drug labeler code: 059130

Change of Sponsor Address

Phibro Animal Health
65 Challenger Rd., 3d floor
Ridgefield Park, NJ 07660
Drug Labeler Code: 066104

Change of Trade Name

NADA Number(s): 065-505

Trade Name: Pro-Pen G

Addition of Patent Number

NADA Number(s): 141-224 & 141-225

Patent Number:	**Expiration Date:**
5,631,298	May 20, 2014

Notice(s)

Guidance for Industry: "Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA)"

The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #173 entitled ``Guidance for Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA)." This guidance describes how FDA intends to implement the Federal Food, Drug, and Cosmetic Act (the act) as it relates to animal drug sponsor fees. Electronic copies of the guidance document entitled ``Guidance for Industry: Animal Drug Sponsor Fees Under the Animal Drug User Fee Act" may be obtained from the CVM home page (http://www.fda.gov/cvm) and from the Division of Dockets Management Web site (http://www.fda.gov/ohrms/dockets/default.htm). Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. For further information: David Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: dnewkirk@cvm.fda.gov.

Comments on agency guidance documents are welcome at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance via the Internet at http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

Public Meeting on Animal Feed Safety System

The Food and Drug Administration (FDA) is announcing a public meeting to discuss our progress on development of a comprehensive, risk-based Animal Feed Safety System (AFSS) describing how animal feeds (individual ingredients and mixed feeds) should be manufactured, distributed, and used to minimize risks to humans and animals. We are seeking comments and assistance in our consideration of this safety program to effectively minimize the hazards to public health posed by animal feed products.

The public meting will be held on Tuesday, April 5, 2005, from 8 a.m. to 5 p.m., and Wednesday, April 6, 2005, from 8 a.m. to 12:15 p.m. You may submit written or electronic comments at any time, but they would be most helpful if received on or before March 4, 2005. The public meeting will be held at The Crowne Plaza, 655 North 108th Ave., Omaha, NE 68154, 402-496-0850.

You may submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Follow the instructions for submitting comments. You can view comments FDA has received on the Internet at http://www.fda.gov/ohrms/dockets/. For general information: Zoe Gill, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6867, FAX: 240-453-6882, or e-mail: zoe.gill@fda.gov. For information about registration: Brenda Boateng, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6850, FAX: 240-453-6882, or e-mail: brenda.boateng@fda.gov. Registration forms are available on the Division of Dockets Management Web site at http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm.

VICH GL-37: "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing "

The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry #160 entitled ``Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing" (VICH GL-37). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is intended to establish recommendations for internationally harmonized repeat-dose chronic toxicity testing.

Submit written or electronic comments at any time. Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. For further information contact: Louis T. Mulligan, Center for Veterinary Medicine (HFV-153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6984, e-mail: lmulliga@cvm.fda.gov.